**HED DOC. NO. 012833**

**27-AUG-1998**

**MEMORANDUM**

**SUBJECT:** ***BUTYLATE*** - Report of the FQPA Safety Factor Committee.

**FROM:** Brenda Tarplee, Executive Secretary
FQPA Safety Factor Committee
Health Effects Division (7509C)
and
Jess Rowland, Executive Secretary
Hazard Identification Assessment Review Committee
Health Effects Division (7509C)

**THROUGH:** Ed Zager, Chairman
FQPA Safety Factor Committee
Health Effects Division (7509C)

**TO:** Whang Phang, Branch Senior Scientist
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**PC Code: 041405**

The Health Effects Division (HED) FQPA Safety Factor Committee met on August 17, 1998 to evaluate the hazard and exposure data for Butylate and recommend application of the FQPA Safety Factor (as required by Food Quality Protection Act of August 3, 1996), to ensure the protection of infants and children from exposure to this pesticide. The Committee recommended that the 10-fold safety factor for increased susceptibility of infants and children should be removed for this pesticide.

## I. HAZARD ASSESSMENT

1. Determination of Susceptibility

The Hazard Identification Assessment Review Committee (HIARC) determined that the available studies **indicated no increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to Butylate.** In the prenatal developmental toxicity studies in rats and rabbits and the two-generation reproduction study in rats, toxicity to the offspring occurred at equivalent or higher doses than in maternal animals (*Memorandum:* P.Chin to V. Dobozy dated June 25, 1998; HED Doc. No. 012729).

2. Adequacy of Toxicity Database

There are **no data gaps** for the assessment of the effects of Butylate following *in utero* and/or postnatal exposure. Based on the toxicity profile, a developmental neurotoxicity study in rats was not required by the HIARC (HED Doc. No. 012729).

## II. EXPOSURE ASSESSMENT AND RISK CHARACTERIZATION

1. Dietary Exposure Considerations

Butylate is a soil incorporated selective herbicide registered for use on field corn, sweet corn, and popcorn. Permanent tolerances are established for residues of Butylate *per se*, in/on corn (field, sweet, and pop) at 0.1 ppm (40 CFR §180.232). There are no established or proposed Codex MRLs.

Transfer of residues to meat, milk, poultry, and eggs is not expected and no tolerances for these commodities are established or proposed.

No monitoring data or percent crop treated (%CT) information are currently available for Butylate. In field trial studies with Butylate, no detectable residues were found.

The HED Dietary Risk Evaluation System (DRES) was used to assess the risk from chronic dietary exposure to Butylate in food. The very conservative assumption was made that all commodities contain residues of Butylate at the level of the tolerance. This results in an overestimate of dietary exposure. The acute dietary risk assessment is pending but is also expected to be an overestimate since tolerance level residues and 100 %CT will be used in the analysis.

2. Drinking Water Exposure Considerations

The environmental fate data base for Butylate is incomplete. Preliminary data, however, indicate that Butylate is mobile to moderately mobile in soil so that the runoff to surface water following a rainfall event is possible when Butylate is applied as a preemergence herbicide or shortly after planting. The parent compound dissipates primarily by volatilization from soil and once in the atmosphere, Butylate may be transported in fogs, mists, and rainwater.

Although both ground and surface water monitoring data are available from areas where Butylate is applied to corn (USGS/NAWQA), EFED recommends that modeling estimates be used for both surface and ground water in exposure assessments since there is currently no standard procedure for determining acute and chronic values from monitoring data. Estimated Environmental Concentrations (EECs) have been calculated for ground and surface water based on the current EFED first level screening models, SCI-GROW and GENEEC respectively.

Concentrations of Butylate reported in both surface water and ground water monitoring data are lower than the levels in the environment predicted using GENEEC and SCI-GROW2. This could be due to the fact that neither GENEEC nor SCI-GROW2 take into account volatility from soil or water (based on laboratory data, Butylate dissipates primarily by volatility from soil). Modeling estimates would likely be lower if volatility were taken into account. The monitoring information for surface water and ground water is more consistent with the environmental fate data and chemical properties than the modeling estimates.

3. Residential Exposure Considerations

There are currently no registered residential uses for Butylate.

## III. SAFETY FACTOR RECOMMENDATION AND RATIONALE

1. Recommendation of the Factor

The Committee recommended that the **10x factor** for increased susceptibility of infants and children (as required by FQPA) should be **removed.**

2. Rationale for Selection of the FQPA Factor

The Committee recommended that the10x Safety Factor should be removed since: 1) the toxicology data base is complete; 2) the developmental and reproductive toxicity data did not indicate increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure; 3) unrefined dietary exposure estimates (assuming all commodities contain tolerance level residues) will overestimate dietary exposure; 4) modeling data are used for ground and surface source drinking water exposure assessments resulting in estimates considered to be upper-bound concentrations; and 5) there are currently no registered residential uses for Butylate.